

Customer No. 22,852  
Attorney Docket No. 04853.0059-01000

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: )  
Kazunari TAIRA et al. )  
Application No.: To be assigned ) Prior Group Art Unit: 1635  
(Divisional of Application No. ) Prior Examiner: K. Lacourciere  
09/763,590) )  
Filed: April 9, 2004 )  
For: EXPRESSION SYSTEMS FOR )  
TRANSCRIPTION OF )  
FUNCTIONAL NUCLEIC ACID )

**Mail Stop Patent Application**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§1.56 and 1.97(b), Applicants bring to the Examiner's attention the documents listed on attached Form PTO-1449. This Information Disclosure Statement is being filed within three months of the filing date of this application.

Applicants respectfully request that the Examiner consider the documents listed and indicate that they were considered by making an appropriate notation on the attached form. The listed documents were provided to the Patent Office or cited by the Examiner in prior parent Application No. 09/763,590, filed February 26, 2001, which is relied upon by Applicants for priority under 35 U.S.C. § 120. Accordingly, Applicants

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have not provided additional copies of these documents in this submission. 37 C.F.R. § 1.98(d).

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: April 9, 2004

By:

  
M. Todd Rands  
Reg. No. 46,249

**INFORMATION DISCLOSURE CITATION**  
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**U.S. PATENT DOCUMENTS**

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	5,670,361	9/23/97	Wong-Staal et al.	435	240.2	

**FOREIGN PATENT DOCUMENTS**

	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	WO 94/00012	Jan. 6, 1994	WIPO			
	WO 96/22368	Jul. 25, 1996	WIPO			

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	Adachi, et al, "Production of Acquired Immunodeficiency Syndrome-Associated Retrovirus in Human and Nonhuman Cells Transfected with an Infectious Molecular Clone," <i>Journal of Virology</i> , 59(1): 284-291 (1986).
	Adeniyi-Jones, et al, "Generation of Long Read-Through Transcripts <i>in vivo</i> and <i>in vitro</i> by Deletion of 3' Termination and Processing Sequences in the Human tRNA <sub>i</sub> <sup>met</sup> Gene," <i>Nucleic Acids Res.</i> , 12: 1101-1115 (1984).
	Agrawal et al., <i>Molecular Medicine Today</i> , 6: 72-81 (2000).
	Anderson, <i>Nature</i> , 392: 25-30 (1998).
	Arnold, et al, "The Human tRNA <sup>val</sup> Gene Family: Organization, Nucleotide Sequences and Homologous Transcription of Three Single-Copy Genes," <i>Gene</i> , 44: 287-297 (1986).
	Arts, et al., "Identification of a Nuclear Export Receptor for tRNA," <i>Curr. Biol.</i> , 8: 305-314 (1998).
	Bertrand, et al. "Can Hammerhead Ribozymes be Efficient Tools to Inactivate Gene Function?," <i>Nucleic Acids Res.</i> , 22: 293-300 (1994).
	Bertrand, et al., "Anti-HIV Therapeutic Hammerhead Ribozymes: Targeting Strategies and Optimization of Intracellular Function," in <i>Nucleic Acids Molecular Biology: Catalytic RNA</i> 310-313 (Eckstein and Lilley eds., 1996).
	Bertrand, et al., "The Expression Cassette Determines the Functional Activity of Ribozymes in Mammalian Cells by Controlling their Intracellular Localization," <i>RNA</i> , 3: 75-88 (1997).
	Boelens, et al., "Nuclear Retention of RNA as a Mechanism for Localization," <i>RNA</i> , 1(3): 273-283 (1995).
	Branch, <i>TIBS</i> , 23: 45-50 (1998).

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	Cotten, et al, "Ribozyme Mediated Destruction of RNA <i>in vivo</i> ," <i>The EMBO Journal</i> , 8(12): 3861-3866 (1989).
	Dahm, et al., "Role of Divalent Metal Ions in the Hammerhead RNA Cleavage Reaction," <i>Biochemistry</i> , 30(39): 9464-9469 (1991).
	Dahm, et al, "Evidence for the Role of Solvated Metal Hydroxide in the Hammerhead Cleavage Mechanism," <i>Biochemistry</i> , 32 (48): 13040-13045 (1993).
	Domi et al., "Transcripts Containing A Small Anti-HIV Hammerhead Ribozyme That Are Active In The Cell Cytoplasm But Inactive <i>In Vitro</i> As Free mRNAs," <i>Biochimie</i> , 78: 654-662, 1996.
	Dropulić, et al., "Functional Characterization of a U5 Ribozyme: Intracellular Suppression of Human Immunodeficiency Virus Type 1 Expression," <i>Journal of Virology</i> , 66(3): 1432-1441 (1992).
	European Search Report for Application No. 99940588.9, mailed October 21, 2002.
	Ferbeyre, et al, "Cell Cycle Arrest Promotes <i>trans</i> -Hammerhead Ribozyme Action in Yeast," <i>The Journal of Biological Chemistry</i> , 271(32):19318-19323 (1996).
	Fujita, et al, "Discrimination of a Single Base Change in a Ribozyme Using the Gene for Dihydrofolate Reductase as a Selective Marker in <i>Escherichia coli</i> ," <i>Proceedings of the National Academy of Sciences</i> , 94(2): 391-196 (1997).
	Gebhard, et al, "Use of a Nonviral Vector to Express a Chimeric tRNA-Ribozyme Against Lymphocytic Choriomeningitis Virus: Cytoplasmic Accumulation of a Catalytically Competent Transcript but Minimal Antiviral Effect," <i>Antisense &amp; Nucleic Acid Drug Development</i> , 7(1): 3-11 (1997).
	Good, et al., "Expression of Small, Therapeutic RNAs in Human Cell Nuclei," <i>Gene Therapy</i> , 4(1): 45-54 (1997).
	Green, et al., <i>J. Am Coll. Surg.</i> , 191(1): 93-105 (2000).
	Guerrier-Takada, et al., "The RNA Moiety of Ribonuclease P is the Catalytic Subunit of the Enzyme," <i>Cell</i> , 35(3): 849-857 (1983).
	Hamblet, et al., "Mitochondrial DNA Deletion Analysis: A Comparison of PCR Quantitative Methods," <i>Biochemical and Biophysical Research Communications</i> , 207(2): 839-847 (1995).
	Haseloff et al., "Simple RNA Enzymes with New and Highly Specific Endoribonuclease Activities," <i>Nature</i> , 334(6183): 585-591 (1988).
	Homann et al., "Incorporation Of The Catalytic Domain Of A Hammerhead Ribozyme Into Antisense RNA Enhances Its Inhibitory Effect On The Replication Of Human Immunodeficiency Virus Type 1," <i>Nucleic Acids Research</i> , 21: 2809-2814, 1993.
	Huang, et al., "Role of Polyadenylation in Nucleocytoplasmic Transport of mRNA," <i>Molecular and Cellular Biology</i> , 16(4): 1534-1542 (1996).
	Inokuchi, et al., "A Hammerhead Ribozyme Inhibits the Proliferation of an RNA Coliphage SP in <i>Escherichia coli</i> ," <i>The Journal of Biological Chemistry</i> , 269(15): 11361-11366 (1994).

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	Ilves, et al., "Retroviral Vectors Designed for Targeted Expression of RNA Polymerase III-Driven Transcripts: A Comparative Study," <i>Gene</i> , 171(2): 203-208 (1996).
	Jen, et al., <i>Stem Cells</i> , 18: 307-319 (2000).
	Jennings, et al., "Inhibition of SV40 Replicon Function by Engineered Antisense RNA Transcribed by RNA Polymerase III," <i>The EMBO Journal</i> , 6(10): 3043-3047 (1987).
	Kawasaki, et al., "Selection of the Best Target Site for Ribozyme-Mediated Cleavage Within a Fusion Gene for Adenovirus E1A-Associated 300 kDa Protein (p300) and Luciferase," <i>Nucleic Acids Research</i> , 24(15): 3010-1016 (1996).
	Kawasaki, et al., "Distinct Roles of the Co-Activators p300 and CBP in Retinoic-Acid-Induced F9-Cell Differentiation," <i>Nature</i> , 393: 284-289 (1998).
	Kruger, et al., "Self-Splicing RNA: Autoexcision and Autocyclization of the Ribosomal RNA Intervening Sequence of Tetrahymena," <i>Cell</i> , 31(1): 147-157 (1982).
	Lott, et al., "A Two-Metal Ion Mechanism Operates in the Hammerhead Ribozyme-Mediated Cleavage of an RNA Substrate," <i>Proceedings of the National Academy of Sciences</i> , 95(2): 542-547 (1998).
	Ohkawa, et al., "Importance of Independence in Ribozyme Reactions: Kinetic Behavior of Trimmed and of Simply Connected Multiple Ribozymes with Potential Activity Against Human Immunodeficiency Virus," <i>Proceedings of the National Academy of Sciences</i> , 90(23): 11302-11306 (1993).
	Ojwang, et al., "Inhibition of Human Immunodeficiency Virus Type 1 Expression by a Hairpin Ribozyme," <i>Proceedings of the National Academy of Sciences</i> , 89(22): 10802-10806 (1992).
	Ozawa, et al., "Quantitative Determination of Deleted Mitochondrial DNA Relative to Normal DNA in Parkinsonian Striatum by a Kinetic PCR Analysis," <i>Biochemical and Biophysical Research Communications</i> , 172(2): 483-489 (1990).
	Perriman, et al., "Effective Ribozyme Delivery in Plant Cells," <i>Proceedings of the National Academy of Sciences</i> , 92(13): 6175-6179 (1995).
	Pontius, et al., "Observations on Catalysis by Hammerhead Ribozymes are Consistent with a Two-Divalent-Metal-Ion Mechanism," <i>Proceedings of the National Academy of Sciences</i> , 94(6): 2290-2294 (1997).
	Prislei, et al., "Use of Adenoviral VAI Small RNA as a Carrier for Cytoplasmic Delivery of Ribozymes," <i>RNA</i> , 3(6): 677-687 (1997).
	Rossi, et al., "RNA Enzymes (Ribozymes) as Antiviral Therapeutic Agents," <i>Trends in Biotechnology</i> , 8: 179-183 (1990).
	Rossi et al., "Ribozymes as Anti-HIV-1 Therapeutic Agents: Principles, Applications, And Problems," <i>AIDS Research and Human Retroviruses</i> , 8: 183-189, 1992.
	Rossi, "Controlled, Targeted, Intracellular Expression of Ribozymes: Progress and Problems," <i>Trends in Biotechnology</i> , 13: 301-306 (1995).

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	Sakamoto et al., "Intracellular Cleavage Of Hepatitis C Virus RNA And Inhibition of Viral Protein Translation By Hammerhead Ribozymes," <i>J. Clin. Invest.</i> , 98: 2720-2728, 1996.
	Sarver, et al., "Ribozymes as Potential Anti-HIV-1 Therapeutic Agents," <i>Science</i> , 247: 1222-1225 (1990).
	Shimada, et al., "Targeted and Highly Efficient Gene Transfer into CD4 Cells by a Recombinant Human Immunodeficiency Virus Retroviral Vector," <i>Journal of Clinical Investigations</i> , 88: 1043-1047 (1991).
	Smith, et al., "Transfer RNA in Reticulocyte Maturation," <i>Biochimica et Biophysica Acta</i> , 655(2): 195-198 (1981).
	Sullenger, et al., "Expression of Chimeric tRNA-Driven Antisense Transcripts Renders NIH 3T3 Cells Highly Resistant to Moloney Murine Leukemia Virus Replication," <i>Molecular and Cellular Biology</i> , 10(12): 6512-6523 (1990).
	Sullenger, et al., "Tethering Ribozymes to a Retroviral Packaging Signal for Destruction of Viral RNA," <i>Science</i> , 262: 1566-1569 (1993).
	Sun et al., "Ribozyme-Mediated Suppression of Moloney Murine Leukemia Virus And Human Immunodeficiency Virus Type I Replication In Permissive Cell Lines," <i>Proc. Natl. Acad. Sci. USA</i> , 91: 9715-9719, 1994.
	Taira, et al., "Construction of a Novel RNA-Transcript-Trimming Plasmid Which can be Used both <i>in vitro</i> in Place of Run-Off and (G)-Free Transcriptions and <i>in vivo</i> as Multi-Sequences Transcription Vectors," <i>Nucleic Acids Research</i> , 19(19): 5152-5130 (1991).
	Thomas, et al., "Site-Directed Mutagenesis by Gene Targeting in Mouse Embryo-Derived Stem Cells," <i>Cell</i> , 51(3): 503-512 (1987).
	Thompson, et al., "Improved Accumulation and Activity of Ribozymes Expressed from a tRNA-Based RNA Polymerase III Promoter," <i>Nucleic Acids Research</i> , 3(12): 2259-2268 (1995).
	Tobian et al., "tRNA Nuclear Transport: Defining the Critical Regions of Human tRNA <sub>i</sub> <sup>met</sup> by Point Mutagenesis," <i>Cell</i> , 43: 415-422 (1985).
	Uhlenbeck, "A Small Catalytic Oligoribonucleotide," <i>Nature</i> , 328 (6131): 596-600 (1987).
	Verma et al., <i>Nature</i> , 392: 25-30 (1998).
	Weerasinghe et al., "Resistance To Human Immunodeficiency Virus Type I (HIV-1) Infection In Human CD4+ Lymphocyte-Derived Cell Lines Conferred By Using Retroviral Vectors Expressing An HIV-1 RNA-Specific Ribozyme," <i>J. Virol.</i> , 65: 5531-5534, 1991.
	Yamada, et al., "Activity and Cleavage Site Specificity of an Anti-HIV-1 Hairpin Ribozyme in Human T Cells," <i>Virology</i> , 205(1): 121-126 (1994).
	Yamada, et al., "Intracellular Immunization of Human T Cells with a Hairpin Ribozyme Against Human Immunodeficiency Virus Type 1," <i>Gene Therapy</i> , 1(1): 38-45 (1994).

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	Yates, et al., "A cis-Acting Element from the Epstein-Barr Viral Genome that Permits Stable Replication of Recombinant Plasmids in Latently Infected Cells," <i>Proceedings of the National Academy of Sciences</i> , 81(12): 3806-3810 (1984).
	Yu, et al., "A Hairpin Ribozyme Inhibits Expression of Diverse Strains of Human Immunodeficiency Virus Type 1," <i>Proceedings of the National Academy of Sciences</i> , 90(13): 6340-6344 (1993).
	Zhao, et al., "Generating Loss-of-Function Phenotypes of the <i>fushi tarazu</i> Gene with a Targeted Ribozyme in <i>Drosophila</i> ," <i>Nature</i> , 365(6445): 448-451 (1993).
	Zhou, et al., "Ribozyme Mechanism Revisited: Evidence Against Direct Coordination of a Mg <sup>2+</sup> Ion with the pro-R Oxygen of the Scissile Phosphate in the Transition State of a Hammerhead Ribozyme-Catalyzed Reaction," <i>Journal of the American Chemical Society</i> , 118(37): 8969-8970 (1996).
	Zhou, et al., "Explanation by the Double-Metal-Ion Mechanism of Catalysis for the Differential Metal Ion Effects on the Cleavage Rates of 5'-oxy and 5'-thio Substrates by a Hammerhead Ribozyme," <i>Proceedings of the National Academy of Sciences</i> , 94(26): 14343-14348 (1997).
	Zhou, et al., "The Hydrolysis of RNA: From Theoretical Calculations to the Hammerhead Ribozyme-Mediated Cleavage of RNA," <i>Chemical Reviews</i> , 98(3): 991-1026 (1998).
Examiner	Date Considered
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